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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,460	08/04/2003	William J. Ayala		4666

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,460	AYALA, WILLIAM J.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *24-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/4/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's election without traverse of group I, claims 1-23 directed to a sleep regulating system in the reply filed on 6/29/06 is acknowledged. Claims 24-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The non-patent literature references crossed out were not provided by applicant and will not be considered.

Specification

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-23 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited. The relative terminology found throughout the claims, such as prompt release, ample but finite elasticity, close relatives, derivatives, neutral materials, etc. It is not understood what the term ample or close relatives encompass etc. Also, claim 12 recites "substances

pending release due to further development". This reads to predict future improvements or modifications. The instant claims define the sleep regulation system with functional limitations that are met in the prior art for tablet formulations.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: The pharmaceutical agent or combination of agents that would be used to treat ADD of ADHD. The claim does not allow one ordinarily skill in the art to realize the necessary steps, precautions and use of the sleep regulating system of the instant claims for treatment of Attention Deficit Disorder and Attention Hyperactive Disorder.

3. Claim 14 recites the limitation "gas-generating substances" such as sodium bicarbonate, mild acids such as citric acid and sodium dihydrogen phophate. There is insufficient antecedent basis for this limitation in the claim and specification.

4. Claim 20 recites the limitation "about 5-7.5 hours". There is insufficient antecedent basis for this limitation in the claim and specification.

5. Claim 5 recites the limitation "the behavior of said membrane". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 9-11,14,16 and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Alaux et al. (WO/002000/033835).

3. Alaux et al. (WO/2000/033835) teaches of a zolpidem or salt thereof controlled-release dosage form. The first phase or immediate phase induces the immediate sleep and is from 0-30 min while the second phase or prolonged release is between 2-6 hours (p1, last paragraph; p2, paragraph 2 and 8). The pellet or tablet prepared from spherical granules or pellets may be incorporated into a multilayer tablet with multiple coatings with an inner layer not containing active substance, thus modulating the release profile (p3, paragraph 2 and 11; p4, paragraph 9). The formulation may contain calcium carbonate, citric acid as well as other acceptable excipients while the coating may consist of a diffusion limiting polymer, such as ethyl cellulose (p6, paragraph 10 and 11; p4, paragraph 4).

4. Claim 1-8 are rejected under 35 U.S.C. 102(a) as being anticipate by Hirsh et al. (US 2003/0118648)

5. Hirsh et al. (US 2003/0118648) teaches of a discrete molded (compressed) tablet comprising a therapeutically effective amount of a pharmaceutically active agent for intraoral administration with a second portion located around the first portion with a pharmaceutically active agent. The composition allows for rapid release for absorption of medicament for rapid relief of symptoms followed by a delayed released manner for

the second medicament (p2, [0011] and [0019]). The pharmaceutically active drugs include stimulants or hypnotics, such as zolpidem (p3, [0033]). The instant claims do not distinctly point out what pharmaceutical agent is disclosed.

6. Claim 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Chopinet-Cote et al. (EP 1074249A1).

7. Chopinet-Cote et al. (EP 1074249A1) teaches a tablet system having a core-centered body covered with at least one couple of adjacent layers, one element fully enclosing the other. The enclosed elements have active substance while the enclosing element is devoid of active substance and delays the release of the latter by a no-release period. The enclosing element has an intrinsic porosity that will remain constant while allowing aqueous medium to penetrate and thus a rapid release of active substance (abstract). The enclosed element comes into contact with aqueous medium through the porous coating and is altered in volume due to swelling allowing for a rapid release of the core active agent (p5, [0033]). The oral delivery tablet system for pharmaceutical use is capable of releasing an active substance during a release period of predetermined duration and quantity of active agent followed by a no-release period devoid of active substance then a subsequent release period having a predetermined release rate (p2, [0003]; p4, [0019]). By controlling the amount retarding (no-release) layer, such as cellulose acetate and others listed in the instant claims the lag time can be 3 h up to 6 or 7 h (p 19, [0124] and [0126]). The fast release layer is comprised of active substance and excipients, such as sodium hydrogen carbonate and citric acid that promote fragmentation and disintegration via effervescence (p6, [0039]). Figure 2

provides a schematic of the tablet system comprising a core with active substance, an intermediate layer devoid of active substance and an external coating layer with active substance (p8, [0052]) while figure 3 contains those described in figure 2 and an external coating layer (p9, [0059]). The tablet system may be comprised of a plurality of couples of tablet elements while the cores can be prepared by means of a rotating press machine (p4, [0025]; p5, [0029]). The instant claims do not distinctly point out what pharmaceutical agent is disclosed.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1- 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chopinet-Cote et al. (EP 1074249A1), Hirsh et al. (US 2003/0118648) in view of Baker (US 3,952,741) and Rashid (US 6,200,600B1).

10. Chopinet-Cote et al. (EP 1074249A1) teaches a tablet system having a core-centered body covered with at least one couple of adjacent layers, one element fully enclosing the other. The enclosed elements have active substance while the enclosing element is devoid of active substance and delays the release of the latter by a no-release period as well as that listed above. Chopinet-Cote et al. (EP 1074249A1) does not teach of the semi-permeable membrane having a weak spot/seam for rupture or the filling of a hollow core with an active substance.

11. Hirsh et al. (US 2003/0118648) teaches of a discrete molded (compressed) tablet comprising a therapeutically effective amount of a pharmaceutically active agent for intraoral administration with a second portion located around the first portion with a pharmaceutically active agent as well as that above.

12. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body (column 1, lines 58-59; column 3, lines 61-64). The osmotic device is enclosed in a semi-permeable membrane that allows for a delay between the time of administration to the time of bursting while inhibiting the tendency of the active agent to leach (column 3, lines 49-55). To control this delay a thicker coating or a different material may be applied, such as cellulose acetate, cellulose nitrate or polyvinyl alcohol, as well as those listed in the instant claims (column 5, lines 32-39). Figure 2 shows the osmotic dispenser incorporating a seam or a weak spot (figure 3.) and rupturing may occur along this seam or weak spot (column 4, lines 1-35 and 47-52).

13. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule where the delay time is from 4-8 hr (column 2, lines 17-20) and contains a hole that is drilled into the capsule from the exterior to the interior and filled with active material as well as inert excipients, such as gas releasing material and is coated (claim 29, column 3, lines 1-9; 16-26 and 46-48). The drugs utilized in this device are sedatives and tranquilizers (column 4, lines 31-32). The release of the active material

after it passes out of the stomach is controlled by the coating agent, such as cellulose acetate (column 6, lines 4-5).

14. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the tablet systems of Chopinet-Cote et al. (EP 1074249A1) or Hirsh et al. (US 2003/0118648) with a combination of release systems and pharmaceutically active substances along with the weakened inner core via a seam disclosed by Baker (US 3,952,741). The calculated release of the inner substance depends on the weakened portion of the inner semi-permeable coating. Since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expediate release of the active substance. Also, it is well known that the first-line medication, such as Methamphetamine has been used for the treatment of ADD and ADHD.

15. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents

located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER